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|--|---------------|------------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/039,935   | 11/01/2001    | Robert Eric Montgomery | P1088US11           | 9955             |
| 53/096   | 7590          | 09/01/2009             | EXAMINER            |                  |
| DISCUS DENTAL, LLC<br>8550 HIGUERA STREET<br>CULVER CITY, CA 90232 |               |                        | ROBERTS, LEZAH      |                  |
| ART UNIT   | PAPER NUMBER  |                        |                     |                  |
|  |               |                        | 1612                |                  |
| MAIL DATE  | DELIVERY MODE |                        |                     |                  |
|  |               |                        | 09/01/2009          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |
|------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/039,935 | <b>Applicant(s)</b><br>MONTGOMERY, ROBERT ERIC |
|                              | <b>Examiner</b><br>LEZAH W. ROBERTS  | <b>Art Unit</b><br>1612                        |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 April 2009 and 18 June 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 56,57,61-65,70-76 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 56, 57, 61-65, 70-76 and 78-81 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Applicants' arguments, filed April 22, 2009 and June 18, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claims 56-58, 61, 63, 64, 67-73, 76, 78, 80 and 81 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650). The rejection is maintained. Claims 58 and 67-69 are cancelled. The rejection encompasses claim 74 as supported by the body of the Office Action mailed January 22, 2009.

#### **Applicant's Arguments**

Applicant argues Williams does not disclose a stabilizing agent or an equivalent. Further the peroxygen concentrations are too low to provide effective tooth whitening within 30 minutes. The reference prefers lower concentrations and therefore teaches

away from the instant claims and the compositions of William will not yield effective whitening results within 30 minutes. This is supported by testing comparing Opalescence comprising 10% carbamide peroxide with no stabilizing agent with the compositions of the instant invention. Opalescence exhibited poor performance with regard to color change over the time of the experiment. The compositions of the present claims exhibited superior results. This argument is not persuasive.

Examiner's Response

Although the preferred embodiment of Williams encompasses lower amounts of peroxides, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. See MPEP 2123, I. Williams discloses 10% and therefore suggest using 10% peroxide in the compositions encompassed by the reference and therefore meet the limitation of the instant claims. Although the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Thus the reference's disclosure of 10% is consistent with the In re Peterson decision, therefore making the concentration obvious in view of the reference. In regards to Applicant's comparison, Opalescence uses 10% carbamide peroxide, which releases about 3% hydrogen peroxide, whereas Williams discloses hydrogen peroxide may be one of the peroxygen compounds and therefore may have a concentration of 10%. Even if this was not the case, the amount of hydrogen peroxide is a result effective variable because it is

the active agent that whitens the teeth. It would take no more than the relative skill of one of ordinary skill in the art to adjust the amount of peroxide to obtain the desired results such as being capable of achieving a detectable tooth-bleaching effect within 30 minutes of contact with the a tooth as recited in the instant claims. The Examiner notes that the recitation of "a detectable tooth bleaching effect" encompasses even the slightest change in color of the tooth. The results in terms of Opalescence, although poor, show a change in color was seen when testing Opalescence, and therefore this meets the limitation of the instant claims of "a detectable tooth bleaching effect". Williams also discloses using stabilizing agents by disclosing disodium pyrophosphate may be used in the compositions, which is also a chelating agent. Collins is used to meet the limitation of a static mixer and therefore overcomes the deficiencies of Williams.

2) Claims 62, 75 and 79 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Collin et al. (US 5,033,650) as applied to claims 56-58, 61, 63, 64, 67-74, 76, 78, 80 and 81 in further view of Burke et al. (US 5,292,502). The rejection is maintained.

*Applicant's Arguments*

Applicant argues Burke et al. does not disclose a stabilizing agent or hydrogen peroxide in a concentration that is sufficiently high enough to generate a tooth whitening effect in 30 minutes or less, and therefore, does not cure the deficiencies of Williams et al and Collins et al. This argument is not persuasive.

Examiner's Response

See Examiner's response above in regards to Williams and Collins. Burke is used for its teaching of pH adjusting agents and therefore remedies the deficiencies of Williams and Collins in regard to the types of pH adjusting agents used in oral compositions.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 56, 57, 61, 62, 64, 65 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner (US 5,302,374 already of record) in view of Collin et al. (US 5,033,650).

Wagner discloses an oral care hygiene system comprising a conventional toothpaste dispensed on a toothbrush along with a quantity of an abrasive free dentifrice containing hydrogen peroxide as the an active constituent (see Abstract). The hydrogen peroxide gel includes 0.2% to 10% hydrogen peroxide, Carbomer 940 encompassing instant claim 65, humectant, sweetening agents and deionized water in sufficient quantity. Additionally EDTA may be employed (col. 2, lines 47-66). The second paste comprises water, tetrasodium pyrophosphate encompassing a peroxide stabilizer, and sodium hydroxide encompassing alkaline pH adjusting agent (Example 2). The reference further discloses one factor involved in the mechanism involving the accelerated breakdown of the hydrogen peroxide constituent of the dentifrice is the fact that conventional toothpastes include pH elevating constituents and at elevated pH

levels, hydrogen peroxide decomposes more readily (col. 5, lines 41-46). The reference differs from the instant claims insofar as it does not disclose a multi-chamber vessel comprising a static mixer or that the pH of the compositions ranges from 7 to 10.

Collin et al disclose a multiple barrel dispensing device for intermixing at least two viscous materials and for dispensing the mixed product in a preferred volumetric ratio. The device comprises a syringe having a plurality of elongated storage compartments for independently storing the material to be intermixed and a common head having a separate channel extending from each compartment for discharging stored materials from a common discharge end of said head (col. 2, lines 8-10). It further comprises a nozzle having a common static mixing element. The reference differs from the instant claims insofar as it does not disclose the compositions recited in the instant claims.

It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that intermixes at least two viscous materials and that dispenses the mixed product in a preferred volumetric ratio, as disclosed by the secondary reference.

The prior art does not disclose the exact claimed values of at least 10%, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Thus the reference's disclosure of 10% hydrogen peroxide is consistent with the In re Peterson decision, therefore making the concentration obvious in view of the reference.

In regards to the bleaching mixture being capable of a detectable tooth-bleaching effect within 30 minutes of contact with a tooth, the compositions comprise 10% hydrogen peroxide as recited in the instant claims and therefore it is reasonable to conclude that the compositions of the reference are capable of a detectable tooth-bleaching effect at the recited time.

In regards to the pH, the pH is a result effective variable because controls the breakdown of hydrogen peroxide and hydrogen peroxide decomposes more readily at elevated pH. It would take no more than the relative skill of one of ordinary skill in the art to have adjusted the pH to between 7 and 10 to obtain the desired results such as being capable of achieving a detectable tooth-bleaching effect within 30 minutes of contact with the a tooth as recited in the instant claims.

In regards to the amount of water in the compositions in claim 61, the reference discloses the compositions comprise a sufficient quantity of water. That being said, experimentation to find workable conditions, in this case, a sufficient quantity, generally involves the application of no more than routine skill in the art. See MPEP 2144.05, II. It would have been obvious to one of ordinary skill in the art to have adjusted the amount of water to at least 70% water by weight motivated by the desire to obtain compositions with a sufficient amount of water.

**Obvious Type Double Patenting (Previous Rejection)**

Claims 56-58, 61-65, 67-76 and 78-81 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 18-21 of copending Application No. 11/256654 in view of Collin et al. (US 5,033,650). The rejection is maintained. Claims 58 and 67-69 are cancelled.

**Applicant's Arguments**

Applicant is willing to file a terminal disclaimer and request the Examiner to hold the requirement of a terminal disclaimer in abeyance until one of the sets of claims is found to be allowable.

**Examiner's Response**

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

Claims 56-58, 61-65, 67-76 and 78-81 are rejected.

No claims allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 1612

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612